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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,927	02/19/2002	Thomas Curran	SJ-01-0032	6357

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/078,927	CURRAN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/21/2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10,11,13-15,32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *32* is/are allowed.

6)☒ Claim(s) *1,4-8,10,11 and 13-15* is/are rejected.

7)☒ Claim(s) *2 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-2, 4-8, 10-11, 13-15, 32, and 34 are pending in the application.

[2] Applicant's amendment to the claims, filed on 11/21/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Applicant's amendment to the specification, filed on 11/21/2005, is acknowledged.

[4] Receipt of a sequence listing in computer readable form (CRF) and a paper copy thereof, a statement of the sameness of the CRF and the paper copy thereof, and a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, all filed on 11/21/2005, is acknowledged. It should be noted that applicant has failed to provide an amendment directing entry of the paper copy of the sequence listing into the specification. In response to this Office action, applicant is required to provide such amendment.

[5] A statement that the sequences disclosed in SEQ ID NO:4 and 5 are identical to the sequences disclosed in GenBank Accession Numbers 177281 and 328851, respectively, at the time of filing of the instant application (p. 6, top of the instant response) is acknowledged.

[6] Applicant's arguments filed on 11/21/2005 are acknowledged. Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[7] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

[8] The amendment filed on 11/21/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the last two words of the amendment to the paragraph beginning at line 22 of page 4, which states "dab1 genes." There is no support in the specification for the disclosed GenBank Accession Numbers as "dab1 genes." The disclosed GenBank Accession Numbers teach the respective nucleic acid is an mRNA, not a gene, which encompasses transcriptional regulatory elements and introns.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, Second Paragraph

[9] Claims 1, 4-8, 10-11, and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

Claim 1 (claims 4-8, 10-11, and 13-15 dependent therefrom) is confusing in the recitation of "a serine corresponding to position 491 of the polypeptide encoded by SEQ

ID NO:4 and a serine corresponding to position 515 of the polypeptide encoded by SEQ ID NO:4" as it relates to a Dab1 comprising SEQ ID NO:3. It is unclear as to which serine of a Dab1 comprising SEQ ID NO:3 is intended as "corresponding to" position 491 or 515 of the polypeptide encoded by SEQ ID NO:4. Is the serine of position 491 or 515 intended as being within the sequence of SEQ ID NO:3? If so, which of the five serine residues of SEQ ID NO:3 are intended as being position 491 or 515? It is suggested that applicant clarify the meaning of the claim.

RESONSE TO ARGUMENT: To the extent the instant rejection is related to a previous rejection under 35 U.S.C. 112, second paragraph, (see ¶[11] part [b] at p. 7 of the 8/22/2005 Office action), the following rebuttal is provided. Applicant argues serine at position 491 or 515 of the polypeptide encoded by SEQ ID NO:4 can be identified by an alignment with the murine Dab1 polypeptide sequence.

Applicant's argument is not found persuasive. Applicant acknowledges that "[t]hese serines may occur at slightly different numerical positions on Dab1 polypeptides from other species." It is unclear to the examiner as to how aligning a serine of a sequence to serine 491 or 515 of the polypeptide encoded by SEQ ID NO:4 will allow a skilled artisan to determine whether the aligned serine corresponds to position 491 or 515 of the polypeptide encoded by SEQ ID NO:4 because any serine of any sequence will "align" with serine 491 or 515 of the polypeptide encoded by SEQ ID NO:4. Thus, in accordance with MPEP 2111, the examiner has interpreted the term "a serine corresponding to position 491 of the polypeptide encoded by SEQ ID NO:4 and a serine corresponding to position 515 of the polypeptide encoded by SEQ ID NO:4" as meaning

any serine within a Dab1 polypeptide (as defined in the specification at p. 4, lines 22-23) comprising SEQ ID NO:3. It is suggested that applicant clarify the meaning of the term.

Claim Rejections - 35 USC § 112, First Paragraph

[10] Claims 1, 4-8, 10-11, and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection that is necessitated by amendment.

Claim 1 (claims 4-8, 10-11, and 13-15 dependent therefrom) recites the limitation "Disabled 1 protein (Dab1) comprising SEQ ID NO:3" recites the limitation "SEQ ID NO:4." MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description." As a showing of support for the recited limitation, applicant points to p. 3, lines 25-29 and p. 15, lines 16-17 of the instant specification. While this disclosure provides support for the peptide of SEQ ID NO:3, it fails to support the recited genus of Dab1 polypeptides comprising SEQ ID NO:3. Applicant is invited to show support for the recited limitation in the original application.

[11] The written description rejection of claims 1, 4-8, 10-11, and 13-15 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant argues claim 1 has been amended to include a structural characteristic for the genus of recited Dab1 proteins, *i.e.,* Dab1 comprises SEQ ID NO:3. According to applicant, inclusion of SEQ ID NO:3 into the claims provides a clear definition of the genus of Dab1 proteins.

Applicant's argument is not found persuasive. The specification defines "Dab1" as "an intracellular adapter protein that is phosphorylated by Cdk5 activity and by reelin tyrosine kinase activity" (specification at p. 4, lines 22-23). Thus, in accordance with MPEP 2111, the examiner has interpreted "Dab1" as recited in the claims as meaning any "intracellular adapter protein that is phosphorylated by Cdk5 activity and by reelin tyrosine kinase activity" that comprises SEQ ID NO:3. According to the *Lilly* Court, "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398. The structures of the species of Dab1 polypeptides are defined only by the 14 amino acid peptide of SEQ ID NO:3. Regarding a representative number of species, the specification discloses only two representative species of Dab1 polypeptides as encompassed by the claims, *i.e.,* murine Dab1

encoded by SEQ ID NO:3 and human Dab1 encoded by SEQ ID NO:4. Because the structures are limited only by SEQ ID NO:3, the genus encompasses species that are structurally widely variant and the structures of the two representative species as noted above fail to reflect the variation among the members of the genus. Regarding a common structural feature, while all members of the genus of Dab1 polypeptides comprise the structural feature of the 14 amino acid peptide of SEQ ID NO:3, this structural feature does *not* constitute a "substantial portion" of the genus of recited Dab1 polypeptides. Thus, it is the examiner's position that the specification fails to adequately describe the claimed invention.

[12] The scope of enablement rejection of claims 1, 4-8, 10-11, and 13-15 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the rejection has been obviated in view of the amendment to limit the scope of Dab1 proteins to those comprising SEQ ID NO:3. Applicant argues the specification shows that murine Dab1 is specifically phosphorylated at two serine residues in response to activated Cdk5 and that Exhibit C of the 4/25/2005 response shows that rat Dab1 is phosphorylated at serine 491. In view of this evidence, applicant argues that a skilled artisan could use this method to activity of any Cdk5 as encompassed by the claims and specification.

Applicant's argument is not found persuasive. The breadth of the claims broadly encompasses a method for detecting Cdk5 activity in a sample by determining whether

any serine within *any* "Dab1" polypeptide (as defined in the specification at p. 4, lines 22-23) comprising SEQ ID NO:3 is phosphorylated. The specification discloses only two working examples of such Dab1 polypeptides as defined by the specification and claims whose phosphorylation is indicative of Cdk5-specific activity, *i.e.,* murine Dab1 encoded by SEQ ID NO:4 and human Dab1 as encoded by SEQ ID NO:5 with Cdk5 phosphorylation at position 491 or 515. Other than these two working examples, the specification fails to disclose other "Dab1" polypeptides whose specific phosphorylation can be used to detect Cdk5 activity. In this case, it is highly unpredictable as to whether phosphorylation of *any* serine of *any* "Dab1" polypeptide as broadly encompassed by the claims will provide an indication of Cdk5-specific activity or whether phosphorylation is indicative of some other kinase activity or a combination of kinase activities. Thus, one must first experiment to determine whether all "Dab1" polypeptides as broadly encompassed can be phosphorylated by Cdk5 and which Cdk5 phosphorylatable serines thereof are indicative of Cdk5-*specific* activity. In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability, and the amount of experimentation required, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

Conclusion

[13] Status of the claims:

Claims 1-2, 4-8, 10-11, 13-15, 32, and 34 are pending.

Claims 1, 4-8, 10-11, and 13-15 are rejected.

Claims 2 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 32 is in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Thursday, 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656